Diagnostic and Interventional Imaging (2015) **96**, 1133—1140

ORIGINAL ARTICLE /*Genito-urinary imaging*

Evaluation of tubal microinserts position using 3D ultrasound and pelvic X-ray

D. Moureau[a,*], **N. Laurent**[b], **C. Rubod**[c], **J.P. Lucot**[c], **J. Salleron**[d], **N. Faye**[a]

[a] *Women Medical Imaging Department, Jeanne-de-Flandre Hospital, CHRU de Lille, avenue Eugène-Avinée, 59037 Lille, France*
[b] *Women Medical Imaging Department, Valenciennes Hospital, Lille Nord University, Valenciennes, France*
[c] *Gynecology Department, Jeanne-de-Flandre Hospital, CHRU de Lille, avenue Eugène-Avinée, 59037 Lille, France*
[d] *Department of Biostatistics, EA2694, UDSL, Lille University, Lille, France*

KEYWORDS
Essure microinserts;
Hysteroscopic sterilization;
Three-dimensional ultrasound (3D-US);
Pelvic X-ray;
Hysterosalpingography

Abstract
Purpose: To retrospectively compare three-dimensional ultrasonography (3D-US) and pelvic X-rays to assess the position of tubal sterilization microinserts.
Material and methods: Forty-four patients who underwent tubal sterilization with Essure® microinserts in our institution were included. The microinserts'position was evaluated three months after the procedure using 3D-US and pelvic X-rays. Placement on 3D-US was binary categorized as correct or incorrect and the distance between the two devices was reported. The orientation and symmetric deployment of the microinserts and the distance between the proximal parts of the two devices was assessed on pelvic X-rays. Performance of 3D-US and pelvic X-ray were compared using Mac Nemar test. Comparison of the distance between the two devices measured on pelvic X-rays and 3D-US was made with the paired Student *t* test.
Results: 3D-US images showed microinserts in 93% (41/44). Eighty-six percent (38/44) were correctly positioned on 3D-US and 82% (36/44) on pelvic X-rays. No significant differences between the performances of the two imaging techniques were found. No significant differences for the distance between the two devices measured on pelvic X-ray and 3D-US was found.
Conclusion: 3D-US is a simple, non-ionizing technique, which appears as a promising alternate technique to pelvic X-rays to assess the correct position of Essure® microinserts.

* Corresponding author.
E-mail address: dom83@wanadoo.fr (D. Moureau).

http://dx.doi.org/10.1016/j.diii.2014.12.013

Tubal sterilization is the most commonly used contraceptive method in the world [1]. Hysteroscopic sterilization is a well-tolerated procedure [1,2] avoiding general anaesthesia [3,4] and surgical incision [5] and the Essure® microinserts (Conceptus, Inc., San Carlos, CA, USA) were first approved in the USA in 2002 [6,7]. It is a permanent birth control device with an efficiency rate at 5-years around 99% [8—11].

Optimal positioning of the microinsert is needed to obtain fibrotic reaction and subsequent tubal occlusion. Consequently, correct position is usually ascertained three months after placement [6,12,13]. The imaging techniques used for ascertaining the correct position may vary among countries [13—17]. Hysterosalpingography (remains the gold standard and is currently recommended by the Food and Drug Administration (FDA) [18—21] whereas pelvic X-rays are recommended in Europe [12]. The new recommendations from the manufacturer advise to perform a pelvic X-ray in first intention three months after the procedure. Hysterosalpingography needs to be performed when the procedure is complicated or if pelvic X-rays do not confirm correct positioning of the devices.

According to Thiels et al. [17], two-dimensional (2D-US) and three-dimensional ultrasonography (3D-US) are excellent alternatives to pelvic X-rays or hysterosalpingography to confirm the correct position of the Essure coils 3 months after the procedure [17].

The purpose of our retrospective study was to compare the performance of pelvic X-rays with those of 3D-US to assess the position of Essure microinserts three months after hysteroscopic sterilization.

Materials and methods

Study population

This retrospective study was, approved by our institutional review board. Fifty-two women underwent hysteroscopic sterilization in our institution (University Hospital) between May 2010 and September 2012 inclusively. Patients were excluded if they underwent hysterosalpingography first because of complications or suspected failure during hysteroscopic procedure (1 patient), if they had history of unilateral salpingectomy (2 patients) or if 3D-US was not available for review (5 patients). Finally, 44 women who underwent 3D-US and pelvic X-rays were included in our study.

Tubal sterilization procedure

The sterilization procedure was carried out in an operating room without general anesthesia and in an ambulatory setting. The procedure was performed during the 7th—14th day of the menstrual cycle and a pregnancy test was conducted within 24 hours before the procedure [22].

A rigid hysteroscope, with a camera, was introduced into the uterine cavity and a saline solution was instillated to distend the uterus. Both tubal ostia were identified, and the microinserts were placed into the proximal portion of the fallopian tube using hysteroscopic guidance [12]; the devices were then deployed [22]. The gynaecologists considered that the Essure were correctly positioned when 3—8 coils were visible into the uterine cavity during hysteroscopy.

Imaging procedure

Pelvic X-rays and 3D-US were performed three months after hysteroscopic sterilization.

Plain anterior-posterior pelvic X-ray examination was performed under fluoroscopy and digital images were recorded.

Vaginal ultrasound was performed with a Voluson E8 (General Electric, Vélizy, France) and a 3D vaginal RC 5-9D probe. 2D-US was first performed to study the uterus' morphology, volume of the uterus, presence of uterine fibroids or adenomyosis, endometrial thickness and the ovaries.

Microinserts were identified in 2D mode and their relationship with the interstitial portion of the fallopian tubes and the uterus were analyzed. Maintaining the probe in a sagittal section of the uterus, we then realized a 3D acquisition. The 3D images allowed obtaining a coronal section of the uterus showing the two microinserts on the same image. If the two microinserts were not visualized in the same section, two coronal images were generated.

Hysterosalpingography (HSG) was secondly performed at least three months after hysteroscopic sterilization to verify tubal occlusion only when the microinserts appeared not correctly positioned on pelvic X-rays and/or 3D-US by the radiologist or when they were considered too proximal into the uterine cavity by the gynecologist who performed the hysteroscopic procedure.

An initial pelvic X-ray examination (Opera Swing, Numerix, Créteil, France) was performed before contrast agent administration. A catheter was then used to instillate 10 mL of iodinated contrast material (Hexabrix 320, Guerbet, Roissy-Charles de Gaulle, France, 10 mL) into the uterine cavity and digital images were recorded [18].

Image analysis

The reading of 3D-US, pelvic X-ray and hysteroscopy examinations was retrospectively done by one radiologist with four years of experience. In case of doubtful images a second radiologist with ten years of experience reviewed the images.

On pelvic X-ray examination, two parameters were evaluated. The first parameter was the orientation and symmetrical deployment of the devices on the basis of visualization of both devices in the pelvic area, horizontal orientation without angulation, and symmetrical appearance. The second parameter was the distance between the two proximal markers of the devices, which is normally <4 cm, which represents the average distance between the two tubal ostia.

On 3D-US, three parameters were studied.

The position of the microinserts was considered correct or incorrect (Fig. 1): a correct position consisted of a perfect position with an isthmic portion, an interstitial portion and an intra-uterine portion or a sub optimal position with an isthmic portion and an interstitial portion or with an interstitial portion and an intra-uterine portion. An incorrect position consisted of a distal position with a device into the distal portion of the fallopian tube without interstitial

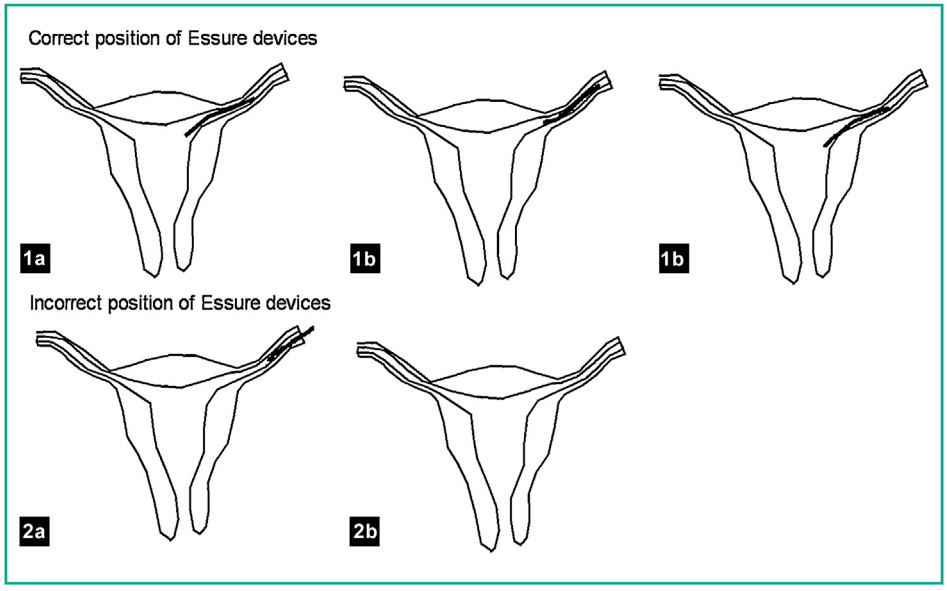

Figure 1. Position of Essure devices on 3D-US. The position is correct if the device is in the interstitial portion of the Fallopian tube: a: perfect position with an isthmic portion, an interstitial portion and an intra-uterine portion; b: suboptimal position with an isthmic portion and an interstitial portion or with an interstitial portion and an intra-uterine portion.

portion or an unseen microinsert or a non-interpretable examination.

The uterus volume was calculated and presence of morphological abnormalities (myoma, adenomyosis) were recorded (Table 1).

Finally, the distance between the two microinserts was calculated by measuring the distance between the two proximal markers of the microinserts in the coronal section of 3D-US. As on pelvic X-ray this distance is normally inferior to 4 cm except if there is a morphological uterus abnormality, which could explain a normal increase of this distance.

The symmetrical deployment and the distance between the proximal markers of the devices were assessed on hysterosalpingography. After contrast medium instillation, we evaluated the presence or absence of tubal occlusion. Tubal patency was reported if the contrast agent was visible into the Fallopian tube past the microinserts or if it leaked into the peritoneal cavity.

Table 1 Population characteristics.

Study population	44
Age	41.7 ± 3.7
2D and 3D-US	44
Pelvic X-ray	44
Hysterosalpingography	9
Intrauterine device	3
Volume of the uterus (cc)	95.7 (29—211)
Uterus morphological abnormalities	Myoma 4 Adenomyosis 9

This table summarizes the characteristics of the population in our study. Forty-four patients underwent two and three dimensional ultrasound (2D-US and 3D-US) and pelvic X-ray.

Statistical analysis

Categorical variables were expressed as proportions, percentages frequency. Continuous variables were expressed as mean and standard deviations.

The Mac Nemar test (SAS version 9.2, Cary, NC 25513, USA) was used to compare the performance of 3D-US and pelvic X-rays. The paired Student *t*-test (SAS version 9.3, Cary, NC 25513, USA) was used to compare the distance between the two proximal markers of the devices in 3D-US and in pelvic X-ray. A P value < 0.05 was considered statistically significant.

Results

Fourty-four women with a mean age of 41.7 years ± 3.7 (SD), a mean gravity of 2.87 ± 0.92 and mean parity of 2.45 ± 2.37 were included. Study population characteristics are described in Table 1.

The correct orientation and symmetric deployment was confirmed in 41/44 patients (93%) on pelvic X-ray examination. The distance between the two proximal markers of the microinserts was <4 cm in 39/44 patients (89%) on pelvic X-ray examination. Finally, pelvic X-ray examination confirmed correct positioning of the two microinserts in 36/44 patients (82%) (Table 2).

On 3D-US, the mean uterus volume was 95.7 cc^3 (±41.09 [SD]) (Table 2).

Morphological abnormalities of the uterus were found in 13/44 patients (30%); four women had myoma and 9 had adenomyosis. The distance between the two devices on 2D-US was measurable only in 13 patients.

When the two microinserts were visible (41/44 women, 93%), 3D-US confirmed their correct position in the interstitial portion of the fallopian tube in 38/41 women (93%)

Table 2 Results for the Essure position observed on pelvic X-ray, 3D-US and hysterosalpyngography in 44 women.

	Correct	Incorrect
Symmetric deployment on pelvic X-ray	41/44 (93%)	3/44 (7%)
Distance between the two proximal markers on pelvic X-ray	39/44 (89%)	5/4 (11%)
Position on pelvic X-ray	36/44 (82%)	8/44 (18%)
Visualization of the two devices on 3D-US	41/44 (93%)	3/44 (7%)
Position on 3D-US	38/44 (86%)	6/44 (14%)
HSG	5/9 (55%)	4/9 (45%)
	Tubal patency	Tubal patency
	3/5 (60%)	0/4 (0%)

This table summarizes the results for the Essure position observed on pelvic X-ray, 3D-US and HSG. According to the criteria of symmetric deployment and the distance inferior to 4 cm between the two proximal markers the Essure microinserts appeared correctly positioned on pelvic X-ray in 36/44 patients (82%). When they were visible and according to the Legendre description [6], the Essure microinserts appeared correctly positioned in 38/44 patients (86%) on 3D-US.

Microinserts were considered incorrectly positioned on 3D-US in 6/44 women (14%) (Fig. 2).

Devices were considered correctly positioned with 3D-US and pelvic X-ray in 33/44 patients (75%) (Fig. 3). In 2/9 patients with adenomyosis, the distance between the two devices was >4 cm while the devices were placed correctly in 3D-US. The uterine volume was enlarged in these patients. One woman with cornual myoma, ipsilateral microinsert was not visualized on 3D-US. In this woman, pelvic X-ray examination confirmed correct positioning.

No significant differences between pelvic X-rays and 3D-US for determining the correct position of microinserts were found ($P = 0.41$). No significant differences between pelvic X-rays and 3D-US to measure the distance between the two proximal markers of the devices were observed ($P = 0.0522$).

Among the nine women who had hysterosalpingography at least three months after hysteroscopic sterilization.

Five were found to have the two microinserts were correctly positioned on 3D-US and on pelvic X-ray, but tubal patency was observed in 3 women (Fig. 4). In four women one or two devices were not correctly positioned on pelvic X-ray and/or 3D-US but no tubal patency was observed.

Discussion

In our study, we compared the performance of pelvic X-ray and 3D-ultrasound, which has never been done in the literature. We showed that the Essure microinserts were correctly positioned in 82% on pelvic X-ray and 86% on 3D-US. If the microinserts were not correctly positioned, patients underwent HSG to confirm tubal occlusion. In the absence of tubal occlusion, another sterilization method can be used.

The hysteroscopic sterilization with Essure devices has become a worldwide alternative to laparoscopic sterilization [1,23—28]. This technique requires an evaluation of the microinsert position three months after the procedure [6,12]. Indeed the fibrotic reaction leading to tubal occlusion and permanent sterilization [29] is only possible if the coils are in the interstitial portion of the fallopian tubes [12].

Essure devices consist of an inner radio opaque stainless steel part, and an outer nickel titanium alloy surrounded by polyethylene terephtalate fibers [6,12,30] (Fig. 5).

The outer spiral is designed to induce fibrotic reaction within 1 to 3 months leading to permanent tubal occlusion [31]. An optimal positioning of Essure device is necessary to obtain fibrotic reaction and subsequently tubal occlusion [12]. After the procedure, the patients have usually moderate pain and spotting [22] but the complications such as expulsion, perforation or another incorrect position of the devices [22] are rare. The pregnancy rate after satisfactory placement reported in the literature is 0.09% [5].

Pelvic X-ray examination is recommended in Europe to check for correct positioning of microinserts. In addition, pelvic X-ray clearly demonstrates the devices and the potential complications such as detachment or fracture of the

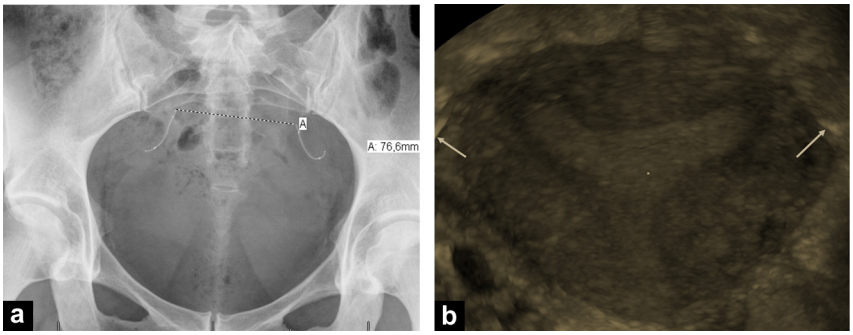

Figure 2. Incorrect position on pelvic X-ray and 3D-US: a: on pelvic X-ray (2a), the distance between the proximal markers of the two devices is greater than 4 cm (A = 76.6 mm); b: On 3D-US, the microinserts are too distal without interstitial portion (white arrows).

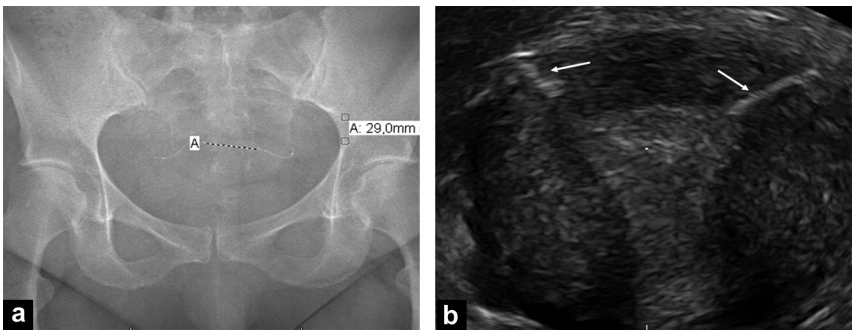

Figure 3. Correct position of Essure device. This figure illustrates a correct position of Essure devices on both pelvic X-ray and 3D-US: a: on pelvic X-ray examinationthe devices has a symmetric deployment and the distance between the two proximal markers was less than 4 cm (A = 29 mm); b: on coronal section generated with 3D-US the microinserts are correctly positioned into the interstitial portion of the Fallopian tube (white arrows).

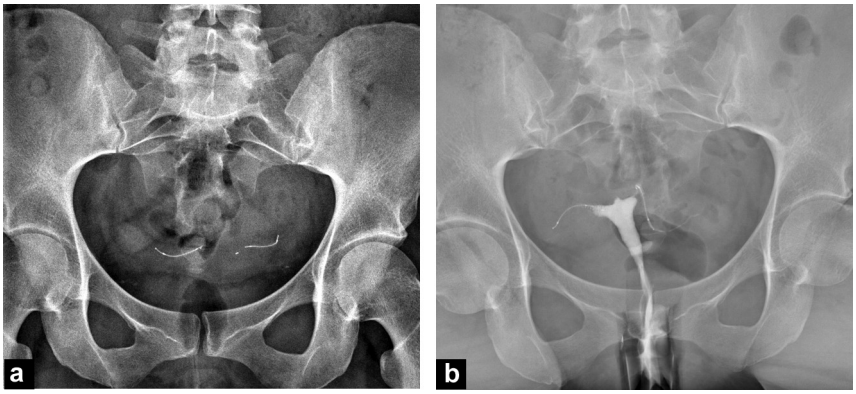

Figure 4. Unilateral tubal patency: a: on pelvic X-ray examination, the devices were symmetric and the distance between the proximal markers of the devices was less than 4 cm; b: on hysterosalpyngography, we observed tubal patency on the left side.

device. In this regard, Franchini et al. showed stable position of microinsert on pelvic X-ray at 3 months and 5 years [29]. However, others authors have reported low degrees of reproducibility for pelvic X-rays [32]. In one study, six readers (three radiologists and three gynaecologists) evaluated 47 pelvic X-ray examinations three months after hysteroscopic sterilization [32]. The reproducibility of the reading expressed as kappa values was 0.52 for radiologists and 0.09 for gynaecologists. The conclusion of this study was to not recommend pelvic X-rays because of poor interobserver agreement even for radiologists.

According to Pachy et al. [1] the pelvic X-ray examination allows assessing the orientation and the symmetry of microinserts but does not appreciate the relation of the microinserts with the surrounding soft tissues. This is an easy, non-expensive and painless but ionizing technique that needs to be taken into account especially for young women (the average dose delivered for a pelvic X-ray was around

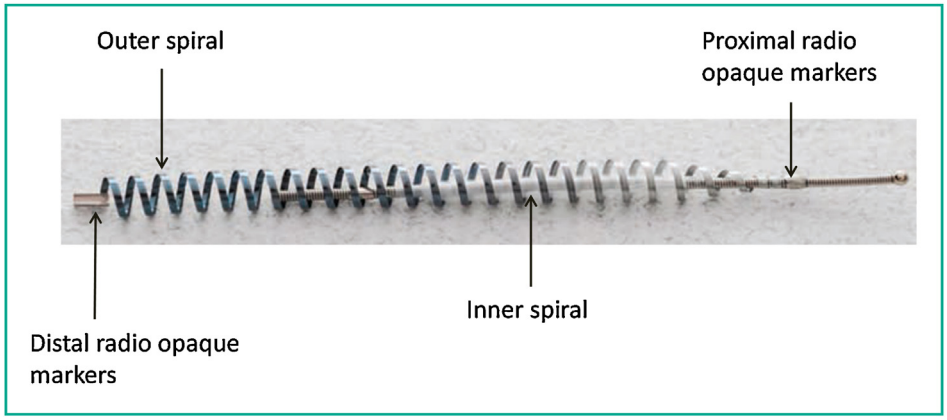

Figure 5. Essure® micro insert. The Essure (Conceptus, Inc., San Carlos, CA, USA) microinsert consists of an inner radio opaque stainless steel part, and an outer nickel titanium alloy surrounded by polyethylene terephtalate fibers.

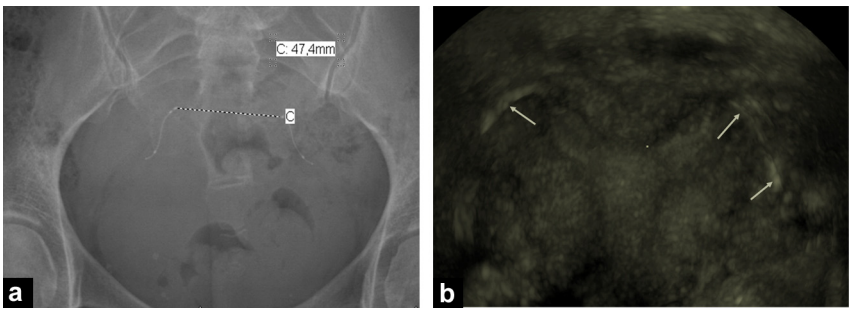

Figure 6. Enlarged uterus with diffuse adenomyosis. On pelvic X-ray (a), the distance between the proximal markers of the two devices was greater than 4 cm (C = 47.4 mm). On the coronal section generated with 3D-US (b), the uterus was enlarged with diffuse adenomyosis but the microinserts (white arrows) were visible into the interstitial portion of the fallopian tubes.

700 cGy.cm^2 or 0.7 mSv in our study). Pelvic X-ray measures the distance between the two devices but has no idea about their real position into the fallopian tubes. In our study, we have shown that this technique failed to represent the real position of microinserts in frequent uterine abnormalities such as enlarged uterus because of adenomyosis, myoma or angulated fallopian tubes (Fig. 6).

The distance can also be falsely right because of reader's mistake in identifying the proximal part of one device.

3D-US seems a promising alternative to pelvic X-ray to confirm the correct position of Essure microinserts. It is an easy, non-expensive and non-ionizing technique. Thiels et al. [17], compared 2D-US and 3D-US to check the position of Essure microinserts in fifty patients. In this study, the 2D and 3D-US examinations allowed to confirm the correct position of microinserts in 84% of cases. As in our study, the position of microinsert was evaluated with a transverse section of the uterus on 2D-US and with a coronal section of the uterus on 3D-US. The 3D acquisition provided the best observation of the relationship between the microinserts, the uterine cavity and the Fallopian tubes. It allowed assessing the morphology and pathology of the uterus and the fallopian tubes that can be responsible of increased distance between the devices or falsely abnormal angulation [1,6,12]. In this study, patients underwent systematically ultrasound but pelvic X-ray was used only in doubtful cases. Unlike our study, there was no comparison between these two imaging techniques.

Legendre et al. [12] compared 3D-US and HSG to analyze microinserts' position in 33 patients and they showed that 3D-US was reliable in this indication.

In our study, HSG was only performed in particular cases corresponding to 20% of the patients. Indeed we considered that this examination was expensive, ionizing and potentially painful to be used systematically. Hysterosalpingography remains the gold standard imaging in USA because it is the only imaging technique that reflects tubal patency. According to Lazarus et al. [18], the hysterosalpingography is necessary to check the position of Essure devices and to confirm tubal occlusion. But since 2002 the success rate of the procedure is superior to 90%, the physiopathology of the fibrosis induced by the microinsert is well known and according to Leary et al. [33], only 15 pregnancies among 66 000 hysteroscopic tubal sterilizations (0.02%) were described in patients with devices correctly positioned on pelvic

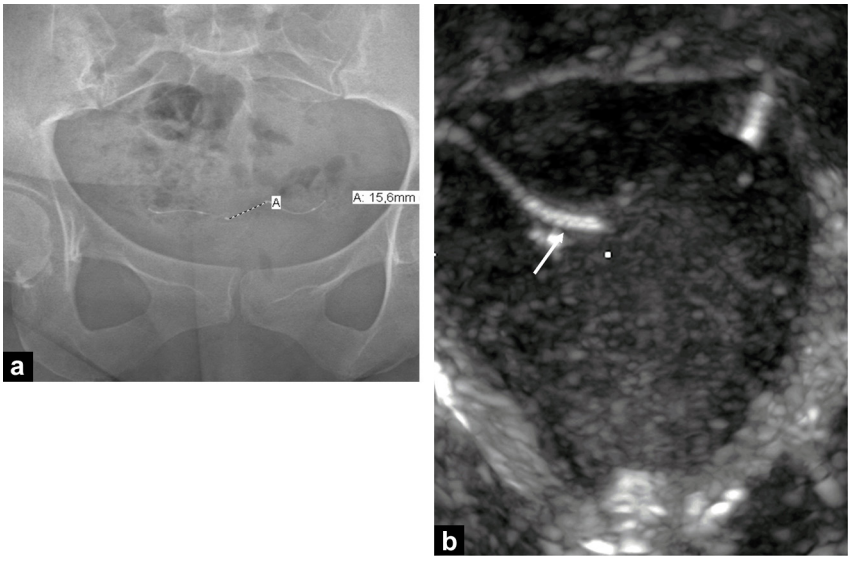

Figure 7. Intra-uterine portion assessment: a: on pelvic X-ray, the devices were symmetric and the distance between the proximal markers of the two devices was less than 4 cm (A = 15.8 mm); b: on 3D-US, the right device (white arrow) was too proximal with an intra uterine portion visible into the cavity.

X-ray, ultrasonography or HSG. Moreover in case of surgical tubal ligation, no control of the tubal occlusion is performed after the procedure even if several cases of intra uterine or ectopic pregnancies were also described [34—36] and the annual pregnancy rate varies from 0 to 2% [37]. In Jost et al.'s study, the total pregnancy rate after Essure procedure was 1.09/1000 (58 pregnancies) but only one case was interpreted as a ''real failure'' of Essure sterilization implant with a correct placement on pelvic X-ray [38].

We observed a tubal patency in HSG in 3/5 patients with correctly positioned microinserts that is also described in the literature [18]. In these cases the intra uterine portion of the devices was superior to 7 mm (mean 15 mm) on 3D-US. This specific criteria is not actually taken into account to assess the correct positioning of the devices. Nethertheless, it may represent a new parameter to assess the position of microinserts and could explain secondary pain, menorrhagia and tubal patency (Fig. 7).

Our study had some limitations. First, the small number of patients with not correctly positioned device because of the success rate of the procedure superior to 90% [31]. This could explain the lack of significant difference observed between pelvic X-ray and 3D-US; indeed to demonstrate the superiority of 3D-US compared to pelvic X-ray, 60 not correctly positioned devices would have been necessary.

Secondly, we did not perform systematically a hysterosalpingography considered as the gold standard in USA to verify the tubal occlusion because it is an ionizing and potentially painful procedure. Furthermore, the manufacturer in Europe does not recommend systematically HSG but only in particular cases [22,39]. Thirdly, our study does not study the new imaging techniques such as the EOS system in pelvis exploration [40].

Finally, our study compared the performance of 3D-US and pelvic X-ray to assess the correct positioning of the devices but it may be interesting to compare 3D-US and 2D-US.

Conclusion

In conclusion, our results show that 3D-US and pelvic X-ray examination have similar capabilities in the evaluation of the positioning of the microinserts. Because 3D-US is a non-ionizing method, which gives more morphological information than pelvic X-rays, it should replace pelvic X-ray examination to evaluate the positioning of the microinserts after hysteroscopic tubal sterilization.

Disclosure of interest

The authors declare that they have no conflicts of interest concerning this article.

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